

3M SOLUPREP- chlorhexidine gluconate and isopropyl alcohol solution

3M Company

3M SoluPrep

Brite Green

Drug Facts

Active ingredients

Chlorhexidine gluconate 2% w/v

Isopropyl alcohol 70% v/v

Purpose

Antiseptic

Antiseptic

Uses

patient preoperative skin preparation:

- for preparation of the skin prior to surgery
- helps reduce bacteria that potentially can cause skin infection

Warnings

For external use only. Flammable, keep away from fire or flame.

To reduce risk of fire; PREP CAREFULLY;

- solution contains alcohol and gives off **flammable vapors**
- avoid getting solution into hairy areas. **Wet hair is flammable.** Hair may take up to 1 hour to dry.
- do not drape or use ignition source (e.g., cautery, laser) until solution is completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair)
- do not allow solution to pool
- remove wet materials from prep area

Allergy Alert: This product may cause a severe allergic reaction. Symptoms may include:

- wheezing/difficulty breathing
- shock
- facial swelling
- hives
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Do not use

- on patients with known allergies to chlorhexidine gluconate or any other ingredient in this product
- for lumbar puncture or in contact with the meninges
- on open skin wounds or as a general skin cleanser

When using this product

- keep out of eyes, ears, and mouth. May cause serious or permanent injury if permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a doctor.
- to avoid skin injury, care should be taken when removing drapes, tapes, etc...applied over film

Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions (follow all directions for use)

- use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.
- discard the applicator after a singular use along with any portion of the solution not required to cover the prepped area. It is not necessary to use the entire amount available.

Getting Patient Ready for Solution:

- use in well-ventilated area
- do not microwave or heat the solution applicator
- apply to clean, completely dry, residue-free, intact skin
- when hair removal is necessary, use a surgical clipper on the morning of the surgery. If a wet shave is used, thoroughly remove all soap residues.

Activating the Applicator:

- remove applicator from package; do not touch sponge
- grasp product by wrapping hand and fingers around the labeled portion of the applicator. Place thumb on the lever.
- with sponge face parallel to the floor, snap level. Allow all fluid to flow into sponge.

When Applying Solution:

- completely wet the treatment area with antiseptic
- **dry surgical sites** (e.g., abdomen or arm): use repeated back-and-forth strokes for 30 seconds
- **moist surgical sites** (e.g., inguinal fold): use repeated back-and-forth strokes for 2 minutes
- maximal treatment area for one applicator is approximately 13 in. x 13 in. (178.8 in²).
- **do not allow solution to pool**; tuck prep towels to absorb solution, and then remove
- avoid getting solution into hairy areas. **Wet hair is flammable.** Hair may take up to 1 hour to dry.
- when prepping skin folds, toes, or fingers, use a sterile-gloved hand to hold skin apart until completely dry. Otherwise, skin may adhere to itself.

After Applying Solution:

- to reduce the risk of fire, **wait until solution is completely dry** (minimum of 3 minutes on hairless skin; up to 1 hour in hair)

While Waiting for Solution to Completely Dry:

- do not drape or use ignition source (e.g., cautery, laser)
- check for pooled solution. Use sterile gauze to soak up pooled solution. Do not blot because it may remove solution from skin.
- remove wet materials from prep area. Replace if necessary.

After Solution is Completely Dry:

- to reduce the risk of fire, begin draping and/or using cautery only after solution is completely dry

and all materials are removed

- if incise drapes are used, apply directly to dry prep
- apply dressing following standard practices

Other information

- store between 15-30 °C (59-86 °F)
- avoid freezing and excessive heat above 40 °C (104 °F)
- The tint will slowly fade from the skin. For early removal of surgical prep use 70% Isopropyl Alcohol.

Inactive ingredients

acetyltri-n-butyl, acrylate copolymer, FD&C blue #1, FD&C yellow #5, purified water USP, Trisodium HEDTA

Questions?

call 1-800-228-3957 (Monday-Friday 7AM-6PM CST). www.3M.com/Medical

3M SoluPrep

Clear

Drug Facts

Active ingredients

Chlorhexidine gluconate 2% w/v

Isopropyl alcohol 70% v/v

Purpose

Antiseptic

Antiseptic

Uses

patient preoperative skin preparation:

- for preparation of the skin prior to surgery
- helps reduce bacteria that potentially can cause skin infection

Warnings

For external use only. Flammable, keep away from fire or flame.

To reduce risk of fire; PREP CAREFULLY;

- solution contains alcohol and gives off **flammable vapors**
- avoid getting solution into hairy areas. **Wet hair is flammable.** Hair may take up to 1 hour to dry.
- do not drape or use ignition source (e.g., cautery, laser) until solution is completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair)
- do not allow solution to pool
- remove wet materials from prep area

Allergy Alert: This product may cause a severe allergic reaction. Symptoms may include:

- wheezing/difficulty breathing

- shock
- facial swelling
- hives
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Do not use

- on patients with known allergies to chlorhexidine gluconate or any other ingredient in this product
- for lumbar puncture or in contact with the meninges
- on open skin wounds or as a general skin cleanser

When using this product

- keep out of eyes, ears, and mouth. May cause serious or permanent injury if permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a doctor.
- to avoid skin injury, care should be taken when removing drapes, tapes, etc...applied over film

Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions (follow all directions for use)

- use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.
- discard the applicator after a singular use along with any portion of the solution not required to cover the prepped area. It is not necessary to use the entire amount available.

Getting Patient Ready for Solution:

- use in well-ventilated area
- do not microwave or heat the solution applicator
- apply to clean, completely dry, residue-free, intact skin
- when hair removal is necessary, use a surgical clipper on the morning of the surgery. If a wet shave is used, thoroughly remove all soap residues.

Activating the Applicator:

- remove applicator from package; do not touch sponge
- with sponge face parallel to the floor, press the cap end of the applicator. Solution will begin to flow into the sponge.
- wait for fluid level to reach indicator line of applicator barrel

When Applying Solution:

- completely wet the treatment area with antiseptic
- **dry surgical sites** (e.g., abdomen or arm): use repeated back-and-forth strokes for 30 seconds
- **moist surgical sites** (e.g., inguinal fold): use repeated back-and-forth strokes for 2 minutes
- maximal treatment area for one applicator is approximately 13 in. x 13 in. (178.8 in²)
- **do not allow solution to pool;** tuck prep towels to absorb solution, and then remove
- avoid getting solution into hairy areas. **Wet hair is flammable.** Hair may take up to 1 hour to dry.
- when prepping skin folds, toes, or fingers, use a sterile-gloved hand to hold skin apart until completely dry. Otherwise, skin may adhere to itself.

After Applying Solution:

- to reduce the risk of fire, **wait until solution is completely dry** (minimum of 3 minutes on hairless skin; up to 1 hour in hair)

While Waiting for Solution to Completely Dry:

- do not drape or use ignition source (e.g., cautery, laser)
- check for pooled solution. Use sterile gauze to soak up pooled solution. Do not blot because it may remove solution from skin.
- remove wet materials from prep area. Replace if necessary.

After Solution is Completely Dry:

- to reduce the risk of fire, begin draping and/or using cautery only after solution is completely dry and all materials are removed
- if incise drapes are used, apply directly to dry prep
- apply dressing following standard practices

Other information

- store between 15-30 °C (59-86 °F)
- avoid freezing and excessive heat above 40 °C (104 °F)

Inactive ingredients

acetyltri-n-butyl, acrylate copolymer, purified water USP, Trisodium HEDTA

Questions?

call 1-800-228-3957 (Monday-Friday 7AM-6PM CST). www.3M.com/Medical

Principal Display Panel - 26mL Green Applicator Label

3M

NDC 17518-080-01

STERILE EO

SoluPrep™

Film-Forming Sterile Surgical Solution

chlorhexidine gluconate (2% w/v) and isopropyl alcohol (70% v/v)

REF 7130

Patient Preoperative Skin Preparation

for large prep areas below the neck

Sterile Solution

Applicator is sterile if package is intact

Brite Green

0.9 fl oz • 26 mL

Single Use

Only

PRESS CAP DOWN

BACK AND FORTH APPLICATION

External use only

Professional use only

Read Drug Facts Information before use

34-8721-0712-2

3M and SoluPrep are trademarks of 3M.

WARNING Flammable

Keep away from fire or flame

To reduce risk of fire,

PREP CAREFULLY:

- Do not use 26-mL applicator for head and neck surgery, or on an area smaller than 11 in. x 11 in. Use a smaller applicator instead.
- Solution contains alcohol and gives off **flammable vapors**
- Avoid getting solution into hairy areas. **Wet hair is flammable.** Hair may take up to 1 hour to dry.
- Do not drape or use ignition source (e.g., cautery, laser) until solution is completely dry (minimum 3 minutes on hairless skin; up to one hour in hair)



- Do not allow solution to pool
- Remove wet materials from prep area

Use: See Drug Facts

Made in U.S.A. by

3M Health Care

2510 Conway Ave.

St. Paul, MN 55144

1-800-228-3957

© 2018, 3M. All rights reserved.

3M

NDC 17518-080-01

STERILE

EO

SoluPrep™

Film-Forming Sterile Surgical Solution

chlorhexidine gluconate (2% w/v) and isopropyl alcohol (70% v/v)

REF

7130

Patient Preoperative Skin Preparation

for large prep areas below the neck

Sterile Solution

Applicator is sterile if package is intact

Brite Green



Single Use
Only

0.9 fl oz • 26 mL

LOT / EXP
IMPRINT AREA
NO ART
(no print layer)



1 PRESS CAP DOWN

2 BACK AND FORTH
APPLICATION

External use only

Professional use only

Read Drug Facts information
before use

34-8721-0712-2

3M and SoluPrep are trademarks of 3M.

Principal Display Panel - 26mL Green Insert Label

3M

STERILE EO

NDC 17518-080-01

SoluPrep™

Film-Forming Sterile Surgical Solution

chlorhexidine gluconate (2% w/v) and isopropyl alcohol (70% v/v)

Patient Preoperative Skin Preparation

for large prep areas below the neck

Sterile Solution

Applicator is sterile if package is intact

Brite Green

SoluPrep™ Surgical Solution is a film-forming, sterile patient preoperative skin preparation. Each unit dose applicator contains 0.9 fl oz (26 mL) of solution which covers a 19.5 in. x 19.5 in. area (approximate from shoulder to groin in an average full size adult). For procedures requiring less coverage, a smaller applicator is available (7133 - Tinted or 7134 - Clear). The smaller applicator size contains 0.36 fl oz (10.5 mL) of solution which covers an approximate 13 in. x 13 in. area. Do not use more than required for the area.

3M recommends all users participate in product in-service training prior to use.

In-servicing is available on video, from your 3M site representative or at the 3M website (www.3m.com).

SoluPrep™ Film-Forming Sterile Surgical Solution is an antimicrobial skin preparation. It is recommended that the Prep remain on the skin after the procedure for continued protection. The prep will gradually wear away. If however early removal is desired, use 70% isopropyl alcohol. Place alcohol soaked gauze for approximately 40 seconds on the prepped area. Lightly rub gauze over area to remove prep.

REF 7130

0.9 fl oz • 26 mL

Made in U.S.A. by

3M Health Care

2510 Conway Ave.

St. Paul, MN 55144

1-800-228-3957

www.3m.com/Medical

Single Use Only

3M and SoluPrep are trademarks of 3M.

@ 2018, 3M. All rights reserved.

Not Made With Natural Rubber Latex



STERILE

EO

NDC 17518-080-01

SoluPrep™

Film-Forming Sterile Surgical Solution

chlorhexidine gluconate (2% w/v) and isopropyl alcohol (70% v/v)

Patient Preoperative Skin Preparation

for large prep areas below the neck

Sterile Solution

Applicator is sterile if package is intact

Brite Green

⚠ WARNING Flammable

Keep away from fire or flame. To reduce risk of fire; PREP CAREFULLY:

- do not use 26-mL applicator for head and neck surgery
- do not use on an area smaller than 13 in. x 13 in. Use a smaller applicator instead.
- solution contains alcohol and gives off **flammable vapors**
- avoid getting solution into hairy areas. **Wet hair is flammable.** Hair may take up to 1 hour to dry.
- do not drape or use ignition source (e.g., cautery, laser) until solution is completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair)
- do not allow solution to pool
- remove wet materials from prep area



SoluPrep™ Surgical Solution is a film-forming, sterile patient preoperative skin preparation. Each unit dose applicator contains 0.9 fl oz (26 mL) of solution which covers a 19.5 in. x 19.5 in. area (approximate from shoulder to groin in an average full size adult).

For procedures requiring less coverage a smaller applicator is available (7133 - Tinted or

For procedures requiring less coverage, a smaller applicator is available (REF 7134 - Clear). The smaller applicator size contains 0.36 fl oz (10.5 mL) of solution which covers an approximate 13 in. x 13 in. area. Do not use more than required for the area. 3M recommends all users participate in product in-service training prior to use. In-servicing is available on video, from your 3M sales representative or at the 3M website (www.3m.com).

SoluPrep™ Film-Forming Sterile Surgical Solution is an antimicrobial skin preparation. It is recommended that the Prep remain on the skin after the procedure for continued protection. The prep will gradually wear away. If however early removal is desired, use 70% isopropyl alcohol. Place alcohol soaked gauze for approximately 40 seconds on the prepped area. Lightly rub gauze over area to remove prep.

REF 7130

0.9 fl oz • 26 mL



(01) 0 03 17518 08001 2

Made in U.S.A. by

3M Health Care

2510 Conway Ave.

St. Paul, MN 55144

1-800-228-3957

www.3M.com/Medical

 **Single Use Only**

3M and SoluPrep are trademarks of 3M.

© 2018, 3M. All rights reserved.



Not Made With
Natural Rubber Latex

34-8716-0114-1

Principal Display Panel – 10.5 mL Applicator Labels

3M

NDC 17518-081-02

STERILE EO

SoluPrep™

Film-Forming Sterile Surgical Solution

chlorhexidine gluconate (2% w/v) and isopropyl alcohol (70% v/v)

REF 7134

Patient Preoperative Skin Preparation

for head, neck, and small prep areas

Sterile Solution

Applicator is sterile if package is intact

Clear

0.36 fl oz • 10.5 mL

Single Use Only

SNAP

BACK AND FORTH APPLICATOR

3M and

SoluPrep

are trademarks

of 3M.

External use only

Professional use only

Read Drug Facts Information before use

34-8721-0718-9

⚠ WARNING
Flammable

Keep away from fire or flame
To reduce risk of fire,
PREP CAREFULLY:

- Solution contains alcohol and gives off **flammable vapors**
- Avoid getting solution into hairy areas. **Wet hair is flammable.** Hair may take up to 1 hour to dry.
- Do not drape or use ignition source (e.g., cautery, laser) until solution is completely dry (minimum 3 minutes on hairless skin; up to one hour in hair)
- Do not allow solution to pool
- Remove wet materials from prep area

Use: See Drug Facts

Made in U.S.A. by
3M Health Care
2510 Conway Ave.
St. Paul, MN 55144
1-800-228-3957
© 2018, 3M. All rights reserved.

3M

SoluPrep™
Film-Forming Sterile Surgical Solution
chlorhexidine gluconate (2% w/v) and isopropyl alcohol (70% v/v)

Patient Preoperative Skin Preparation
for head, neck and small prep areas
Sterile Solution
Applicator is sterile if package is intact

NDC 17518-081-02

STERILE EO

REF 7134

Clear

**LOT / EXP
IMPRINT AREA
NO ART
(no print layer)**

34-8721-0718-9

0.36 fl oz • 10.5 mL

1 SNAP

2 BACK AND FORTH APPLICATION

External use only
Professional use only
Read Drug Facts information before use

Single Use Only
3M and SoluPrep are trademarks of 3M.

Principal Display Panel – 10.5mL Clear Insert Label

3M

STERILE EO

NDC 17518-081-02

SoluPrep™

Film Forming Sterile Solution

chlorhexidine gluconate (2% w/v) and isopropyl alcohol (70% v/v)

Patient Preoperative Skin Preparation

for head, neck, and small prep areas

Sterile Solution

Applicator is sterile if package is intact

Clear

Not Made With Natural Rubber Latex

Single Use Only

SoluPrep™ Surgical Solution is a film-forming, sterile patient preoperative skin preparation. Each unit dose applicator contains 0.36 fl oz (10.5 mL) of solution which covers a 13 in. x 13 in. area.

3M recommends all users participate in product in-service training prior to use. In-servicing is available on video, from your 3M site representative or at the 3M website (www.3m.com).

SoluPrep™ Film-Forming Sterile Surgical Solution is an antimicrobial skin preparation. It is recommended that the Prep remain on the skin after the procedure for continued protection. The prep will gradually wear away. If however early removal is desired, use 70% isopropyl alcohol. Place alcohol soaked gauze for approximately 40 seconds on the prepped area. Lightly rub gauze over area to remove prep.

REF 7134

0.36 fl oz • 10.5 mL

Made in U.S.A. by

3M Health Care

2510 Conway Ave.

St. Paul, MN 55144

1-800-228-3957

www.3m.com/Medical

3M and SoluPrep are trademarks of 3M.

@ 2018, 3M. All rights reserved.

34-8716-0123-2

3M

STERILE

EO

NDC 17518-081-02

SoluPrepTM

Film-Forming Sterile Surgical Solution



Not Made With
Natural Rubber Latex



Single Use Only

chlorhexidine gluconate (2% w/v) and
isopropyl alcohol (70% v/v)

Patient Preoperative Skin Preparation

for head, neck, and small prep areas

Sterile Solution

Applicator is sterile if package is intact

Clear

⚠ WARNING Flammable

**Keep away from fire or flame. To reduce risk of fire;
PREP CAREFULLY:**

- solution contains alcohol and gives off **flammable vapors**
- avoid getting solution into hairy areas. **Wet hair is flammable.** Hair may take up to 1 hour to dry.
- do not drape or use ignition source (e.g., cautery, laser) until solution is completely



cautery, laser) until solution is completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair)

- do not allow solution to pool
- remove wet materials from prep area

Cautery 



SoluPrep™ Surgical Solution is a film-forming, sterile patient preoperative skin preparation. Each unit dose applicator contains 0.36 fl oz (10.5 mL) of solution which covers a 13 in. x 13 in. area.

3M recommends all users participate in product in-service training prior to use. In-servicing is available on video, from your 3M sales representative or at the 3M website (www.3m.com).

SoluPrep™ Film-Forming Sterile Surgical Solution is an antimicrobial skin preparation. It is recommended that the Prep remain on the skin after the procedure for continued protection. The prep will gradually wear away. If however early removal is desired, use 70% isopropyl alcohol. Place alcohol soaked gauze for approximately 40 seconds on the prepped area. Lightly rub gauze over area to remove prep.

REF 7134 0.36 fl oz • 10.5 mL



(01) 0 03 17518 08102 6

Made in U.S.A. by

 **3M Health Care**

123-2

2510 Conway Ave.
St. Paul, MN 55144
1-800-228-3957
www.3M.com/Medical

3M and SoluPrep are trademarks of 3M.
© 2018, 3M. All rights reserved.

34-8716-C

3M SOLUPREP

chlorhexidine gluconate and isopropyl alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17518-080
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	20 mg in 1 mL
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
TRISODIUM HEDTA (UNII: K3E0U7O8KI)	
ACETYLTRIBUTYL CITRATE (UNII: 0ZBX0N59RZ)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17518-080-01	1 in 1 POUCH	10/08/2018	
1		26 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
2	NDC:17518-080-02	1 in 1 POUCH	10/08/2018	
2		10.5 mL in 1 APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA208288	10/08/2018	

3M SOLUPREP

chlorhexidine gluconate and isopropyl alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17518-081
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	20 mg in 1 mL
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ACETYLTRIBUTYL CITRATE (UNII: 0ZBX0N59RZ)	
WATER (UNII: 059QF0KO0R)	
TRISODIUM HEDTA MONOHYDRATE (UNII: 463A7RIB6K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17518-081-02	1 in 1 POUCH	10/08/2018	
1		10.5 mL in 1 APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA208288	10/08/2018	

Labeler - 3M Company (006173082)

Establishment

Name	Address	ID/FEI	Business Operations
3M Company		830016148	ANALYSIS(17518-080, 17518-081)